Utilization Review Policy 149

POLICY: Oncology (Injectable – Programmed Death-Ligand 1) – Bavencio Utilization Management Medical Policy

- Bavencio® (avelumab intravenous infusion – EMD Serono)

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Bavencio, a programmed cell death ligand-1 (PD-L1) blocking antibody, is indicated for the treatment of the following:[1]

- **Merkel cell carcinoma**, in patients ≥ 12 years of age with metastatic disease.
- **Renal cell carcinoma**, in combination with Inlyta® (axitinib tablets), for the first-line treatment of advanced disease.
- **Urothelial carcinoma**, in patients with locally advanced or metastatic disease who have:
  - Disease progression during or following platinum-containing chemotherapy.
  - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
  - Maintenance treatment of locally advanced or metastatic disease that has not progressed with first-line platinum-containing chemotherapy.

Dosing Information

Premedication with an antihistamine and acetaminophen is recommended with the first four infusions of Bavencio.[1] For subsequent Bavencio infusions, premedication is recommended based on clinical judgement and presence/severity of prior infusion reactions. The recommended dose of Bavencio is 800 mg administered as an intravenous infusion over 60 minutes once every 2 weeks until disease progression or unacceptable toxicity. For renal cell carcinoma, Bavencio is used in combination with Inlyta 5 mg taken orally twice daily.

Guidelines

Bavencio is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Bladder Cancer:** Guidelines (version 4.2024 – May 9, 2024) recommend Bavencio as an alternative "Preferred" regimen for second-line therapy (category 2A) for locally advanced or metastatic disease (Stage IV).[2,3] Guidelines also recommend Bavencio as maintenance therapy following platinum-based chemotherapy (category 1). The NCCN Compendium recommends Bavencio, as a single agent, for urothelial carcinoma of the bladder; for upper genitourinary tract tumors (metastatic disease); urothelial carcinoma

of the prostate (metastatic disease); and for primary carcinoma of the urethra (recurrent or metastatic disease) as second-line or maintenance therapy.[3]

- **Gestational Trophoblastic Neoplasm:** Guidelines (version 1.2024 – October 27, 2023) recommend Bavencio as a single agent for multidrug resistant high-risk disease, or recurrent or progressive intermediate trophoblastic tumor.[3,6]
- **Kidney Cancer:** Guidelines (version 1.2025 – July 1, 2024) recommend Bavencio in combination with Inlyta for first-line treatment for relapsed or Stage IV clear cell disease (category 2A).[3,5] For subsequent therapy, Bavencio + Inlyta is a category 3 recommendation.
- **Merkel Cell Carcinoma:** Guidelines (version 1.2024 – November 22, 2023) recommend Bavencio as a "Preferred Regimen" for the treatment of primary locally advanced disease (if curative surgery and curative radiation therapy are not feasible) and for disseminated disease (both category 2A).[3,4] Bavencio is also recommended as "Other Recommended Regimen" for the treatment of recurrent locally advanced or recurrent regional disease if curative surgery or curative radiation therapy are not feasible (both category 2A).
- **Uterine Neoplasms:** Guidelines (version 2.2024 – March 6, 2024) recommend Bavencio, as a single agent, for the second-line and subsequent treatment of recurrent or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.[3,7]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Bavencio. Approval is recommended for those who meet the conditions of coverage in the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Bavencio, as well as the monitoring required for adverse events and long-term efficacy, approval requires Bavencio to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Bavencio is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Merkel Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 12 years of age; AND
B) Patient meets ONE of the following (i, ii, or iii):
   a. Patient has locally advanced disease; OR
   b. Patient has recurrent regional disease; OR
   c. Patient has metastatic (disseminated) Merkel cell carcinoma; AND
C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

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2. Renal Cell Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has relapsed or Stage IV clear cell disease; AND
C) The medication will be used in combination with Inlyta (axitinib tablets); AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

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3. Urothelial Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has locally advanced or metastatic urothelial carcinoma; AND
C) Patient has tried platinum-containing chemotherapy (cisplatin or carboplatin); AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

Other Uses with Supportive Evidence

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4. Endometrial Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient has recurrent or metastatic disease; AND
C) Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors; AND
D) The medication will be used as a single agent; AND
E) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks.

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5. **Gestational Trophoblastic Neoplasia.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has multi-agent chemotherapy resistant disease; AND
   - **C)** The medication will be used as a single agent; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve ONE of the following dosing regimens (A or B):
   - **A)** 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks; OR
   - **B)** 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Bavencio is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Bavencio® intravenous infusion [prescribing information]. Rockland, MA: EMD Serono; March 2024.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 9, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 11, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 11, 2024. Search term: avelumab.
4. The NCCN Merkel Cell Carcinoma Clinical Practice Guidelines in Oncology (version 1.2024 – November 22, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 11, 2024.
5. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – July 1, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 11, 2024.

6. The NCCN Gestational Trophoblastic Neoplasia Clinical Practice Guidelines in Oncology (version 1.2024 – October 27, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 11, 2024.
7. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – March 6, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 11, 2024.
8. You B, Bolze PA, Lotz JP, et al. Avelumab in patients with gestational trophoblastic tumors with resistance to single-agent chemotherapy: Cohort A of the TROPHIMMUN Phase II trial. *J Clin Oncol*. 2020;38:3129-3137.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/19/2023
Annual Revision	**Merkel Cell Carcinoma:** Added patient has locally advanced disease and patient has recurrent regional disease as additional options for approval. **Gestational Trophoblastic Neoplasia:** Added 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks as an additional dosing regimen.	07/24/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024